104TH CONGRESS
2D SESSION

H. RES. 449

Relating to breast implants, the Food and Drug Administration, and breast care.

IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 1996

Mrs. VUCANOVICH (for herself, Mr. CALVERT, Mrs. CLAYTON, Mr. HOBSON, Mr. HUTCHINSON, Mrs. JOHNSON of Connecticut, Mr. LIPINSKI, Mr. MYERS of Indiana, Mr. PETRI, and Mr. WAMP) submitted the following resolution; which was referred to the Committee on Commerce

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RESOLUTION

Relating to breast implants, the Food and Drug Administration, and breast care.

Whereas breast implant safety is a public health issue of fundamental importance, particularly for those women who already have implants and women who are diagnosed with breast cancer facing urgent decisions about reconstruction;

Whereas manufacturers of silicone breast implants are encouraged to pursue the premarket approval application process with the Food and Drug Administration;

Whereas conflicting information has been provided to the public about the safety of silicone gel breast implants;

Whereas the Food and Drug Administration imposed restrictions on the availability and use of breast implants, based on concerns of a possible relationship between silicone gel breast implants and connective tissue disease;

Whereas breast cancer patients seeking reconstruction may only gain access to silicone gel breast implants through participation in a clinical trial under an approved protocol;

Whereas only a small fraction of the post-mastectomy patients in the United States who seek reconstruction have access to silicone gel breast implants through clinical trials;

Whereas research has been undertaken by many prestigious medical centers and universities on the issue of silicone gel breast implants and connective tissue disease;

Whereas controlled scientific studies conducted by these prestigious universities to date show no greater incidence of connective tissue disease in women with implants than those without;

Whereas the Food and Drug Administration has not issued a definitive statement on the relationship between silicone gel breast implants and connective tissue disease;

Whereas the Food and Drug Administration has not provided substantial information on breast care for women with implants;

Whereas the National Cancer Institute has not provided substantial information on breast care for women with implants, waiting for the Food and Drug Administration's lead in this matter; and

Whereas the controversy over silicone gel breast implants has a broader impact on the public health by adversely affect-

ing the supply of raw materials used in other products, such as pacemakers, heart valves, hip and knee joints, and artificial blood vessels: Now, therefore, be it

Resolved, That it is the sense of the House of Representatives that the Food and Drug Administration should take immediate steps to resolve the fears and concerns of women with breast cancer by issuing a definitive statement on the relationship (or lack thereof) between silicone gel breast implants and connective tissue disease, classic auto-immune symptoms, and other serious diseases. In addition, the Food and Drug Administration and the National Cancer Institute should develop recommendations for breast care practices for women with breast implants.

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